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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,539	08/16/2006	Klaus Abraham-Fuchs	32860-001074/US	8488

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EXAMINER

WINSTON III, EDWARD B

ART UNIT	PAPER NUMBER
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3686

MAIL DATE	DELIVERY MODE
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10/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,539	Applicant(s) ABRAHAM-FUCHS ET AL.	
	Examiner EDWARD WINSTON	Art Unit 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>16 August 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular it is not clear “wherein verification, with respect to the selection criteria, takes place automatically when the patient data in the data processing system change”. Examiner notes that there is no verification step in the independent Claim 1. Examiner is uncertain what this limitation is trying to encompass.

Appropriate clarification and correction is required.

2. Claim 4 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular it is not clear “wherein the selection of a patient as a potential participant takes place during a treatment of the patient which is correlated with the medical project, wherein the request is generated during the treatment and transmitted to the patient, and if the patient agrees, the treatment is continued on him as a participant in accordance with the medical project”. Examiner is unclear how the selection of the patient as a potential

participant takes place during treatment of the patient. Examiner is uncertain what this limitation is trying to encompass.

Appropriate clarification and correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by RAO, R., Bharat (WO 03/040878 A2).

CLAIM 1 -

RAO teach(s) a method for selecting and reporting a potential participant for a medical project with selection criteria for patients, said method comprising:

- checking patient data, contained in a data processing system and associated with patients, with respect to the selection criteria; selecting the patient associated with the patient data as a potential participant if the selection criteria are met; and reporting the selected patient as a potential participant. (See at least Abstract, Page 7 || 14-21, Page 8 || 16-24)

CLAIM 2 -

RAO further teach(s) a method as claimed in claim 1,

- wherein verification, with respect to the selection criteria, takes place automatically when the patient data in the data processing system change. (See at least Abstract, Page 2 || 17-19)

CLAIM 3 AND 9 -

RAO further teach(s) a method as claimed in claim 1,

- wherein, in order to conduct the medical project, an agreement of the participant is needed in which when a patient is selected as a potential participant, the data processing system automatically generates a request asking for the participant's agreement, the request is transmitted (i.e. sent out) to the patient, and in the event of an agreement, the patient is selected as a participant and reported. (See at least Abstract, Page 8 || 16-24)

CLAIM 4 AND 10 -

RAO further teach(s) a method as claimed in claim 3 and 9,

- wherein the selection of a patient as a potential participant takes place during a treatment of the patient which is correlated with the medical project, wherein the request is

generated during the treatment and transmitted to the patient, and if the patient agrees, the treatment is continued on him as a participant in accordance with the medical project.

(see at least Page 12 || 7-9 i.e. medical project/ testing a new drug on black males [selection criterion]; Figure 4)

CLAIM 5 and 11 -

RAO further teach(s) a method as claimed in claim 1,

- wherein rules of conduct are assigned to the medical project, and when a patient is selected as a potential participant, the rules of conduct are reported (i.e. details of trail).

(see at least Page 8 || 16-24)

CLAIM 6 and 12-

RAO further teach(s) a method as claimed in claim 5 and 11,

- wherein when a patient is selected as a potential participant, the rules of conduct are assigned to the selected patient (i.e. details of trail). (See at least Abstract, Page 8 || 16-24)

CLAIM 7 and 13-

RAO further teach(s) a method as claimed in claim 5 and 6,

- wherein the rules of conduct are transmitted to a workflow management system. (See at least Page 6 || 20-24; Page 7 || 1-4)

CLAIM 8 and 14 -

RAO further teach(s) a method as claimed in claim 1 and 2,

- wherein a clinical study is conducted as the medical project. (See at least Abstract, Page 12 || 7-9)

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EDWARD WINSTON whose telephone number is (571) 270-7780. The examiner can normally be reached on MONDAY-THURDAY; 9:00AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Conner can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/EBW/
06 October 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686